



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

February 17, 2016

Argite LLC  
c/o Pyxis Regulatory Consulting Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Subject: Data Deficiency  
Product Name: Argite Acetamiprid Technical  
EPA File Symbol: 91127-E  
Application Date: March 16, 2015  
EPA Receipt Date: March 17, 2015  
OPP Decision Number: D-502427

Dear Ms. Tillman,

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in an email dated January 13, 2016, you were notified that the data matrix contained deficiencies. After review of your revised data matrix dated January 15, 2016, the Agency has still found deficiencies. Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **May 2, 2016** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent

submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The proposed label has use sites that are not listed on the cited label 8033-20. Delete the following: Turnip Greens, Clover (ID, OR, and WA only), and Seed Treatment (canola and mustard).

2. Make the following change since the study is no longer compensable:

Mark MRID 45245304 from guideline 870.4100 as OLD rather than PAY

3. The Agency determined the data matrix is missing the following studies that are compensable. Make the following changes and offers to pay:

- a. Add MRID 46255602 to guideline 830.7300
- b. Add MRID's 46255621 and 46255620 to guideline 870.1100
- c. Add MRID 46255603 to guideline 835.4100
- d. Add MRID 48554501 to guideline 835.4200
- e. Add MRID's 46255608 and 45916201 to guideline 850.1010
- f. Add MRID 46729101 to guideline 850.1400
- g. Add MRID 48407701 to guideline 850.2100
- h. Add MRID 49056401 to guideline 850.2200
- i. Add MRID's 46639201 and 48825601 to guideline 850.2300
- j. Add MRID's 45932502 and 45346901 to guideline 850.3030
- k. Add MRID's 45932504, 45932505 and 49342201 to guideline 850.3040
- l. Add MRID 49342201 to guideline SS-1163 and SS-1113
- m. Add MRID 48404401 to guideline 860.1500
- n. Add MRID's 48872402-48872411 to guideline 860.1500 (Citrus [group 10])
- o. Add MRID's 45532301 and 45532302 to guideline 870.4100
- p. Add MRID 46779202 to guideline 870.6300
- q. Add MRID 46255622 to guideline 870.7200
- r. Add MRID 45323001 to guideline 875.2100

4. Your data matrix is missing the following studies that are not compensable. They need to be added but can be marked as OLD

- a. Add MRID's 44988531 and 44988532 to guideline 860.1500 (Cole Leafy Vegetables [group 5])
- b. Add MRID 44988620 to guideline 860.1520
- c. Add MRID 45245306 to guideline 870.3150
- d. Add MRID's 45245302 and 45245303 to guideline 870.3700
- e. Add MRID 45245301 to guideline 870.3800
- f. Add MRID's 44651849-44651851 to guideline 870.5100
- g. Add MRID 45130801 to guideline 870.6200

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on March 7, 2016. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **February 22, 2016** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **February 22, 2016** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **February 22, 2016**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **February 22, 2016** by contacting Jessica Rogala by phone at 703-347-0263, or via email at [rogala.jessica@epa.gov](mailto:rogala.jessica@epa.gov) or Venus Eagle 703-308-8045 or via email at [eagle.venus@epa.gov](mailto:eagle.venus@epa.gov). during the hours of 7 am to 3 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Venus Eagle". The signature is written in dark ink and includes a long horizontal flourish extending to the right.

Venus Eagle, Product Manager 01  
Invertebrate & Vertebrate Branch 3  
Registration Division (7505P)  
Office of Pesticide Programs